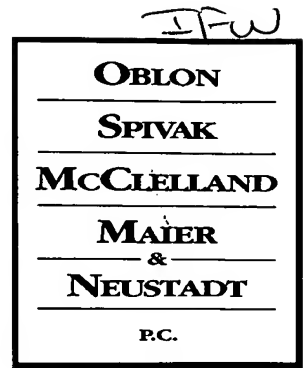




Docket No.: 273056US0PCT

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313



ATTORNEYS AT LAW

RE: Application Serial No.: 10/537,407  
Applicants: Shigehiko IMAGAWA, et al.  
Filing Date: June 2, 2005  
For: ERYTHROPOIETIN PRODUCTION ACCELERATOR  
Group Art Unit: 1645  
Examiner:

SIR:

Attached hereto for filing are the following papers:

**Letter**

**English Translation International Preliminary Report on Patentability**

Our check in the amount of \$0.00 is attached covering any required fees. In the event any variance exists between the amount enclosed and the Patent Office charges for filing the above-noted documents, including any fees required under 37 C.F.R. 1.136 for any necessary Extension of Time to make the filing of the attached documents timely, please charge or credit the difference to our Deposit Account No. 15-0030. Further, if these papers are not considered timely filed, then a petition is hereby made under 37 C.F.R. 1.136 for the necessary extension of time. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Norman F. Oblon

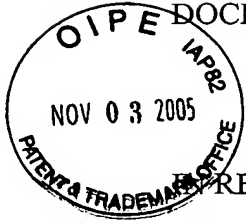
  
\_\_\_\_\_  
Frederick D. Vastine

Registration No. 27,013

Customer Number

**22850**

(703) 413-3000 (phone)  
(703) 413-2220 (fax)



DOCKET NO: 273056US0CONT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

PRE APPLICATION OF :

SHIGEHICO IMAGAWA, ET AL.. :

SERIAL NO: 10/537,407 :

FILED: JUNE 2, 2005

: GROUP ART UNIT: 1645

FOR: ERYTHROPOIETIN PRODUCTION :  
ACCELERATOR

LETTER

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicants wish to make of record the attached International Preliminary Report on  
Patentability. Copies of the references listed therein were filed on June 2, 2005.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Norman F. Oblon

Frederick D. Vastine  
Registration No. 27,013

Customer Number  
**22850**

Tel: (703) 413-3000  
Fax: (703) 413 -2220  
(OSMMN 06/04)

From the INTERNATIONAL BUREAU

**PCT**

NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY  
(CHAPTER I OR CHAPTER II  
OF THE PATENT COOPERATION TREATY)  
(PCT Rule 72.2)

To:

THE PATENT CORPORATE BODY ARUGA PATENT  
OFFICE  
KYODO BLDG.  
3-6, Nihonbashiningyocho 1-Chome  
Chuo-ku, Tokyo 103-0013  
JAPON



Date of mailing ( <i>day/month/year</i> ) 29 September 2005 (29.09.2005)	
Applicant's or agent's file reference KW0112	<b>IMPORTANT NOTIFICATION</b>
International application No. PCT/JP2003/015589	International filing date ( <i>day/month/year</i> ) 05 December 2003 (05.12.2003)
Applicant KOWA CO., LTD. et al	

**1. Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

**2. Transmittal of the copy of the translation to the elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

AZ, CA, CH, CN, EP, GH, KG, KP, KR, MK, MZ, RO, RU, TM

The following elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, BA, BB, BG, BR, BY, BZ, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, ES, FI, GB, GD, GE, GM, HR, HU, ID, IL, IN, IS, JP, KE, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MN, MW, MX, NI, NO, NZ, OA, OM, PG, PH, PL, PT, SC, SD, SE, SG, SK, SL, SY, TJ, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

**3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Authorized officer

Masashi Honda

Facsimile No.+41 22 740 14 35

Facsimile No.+41 22 338 70 10

Translation

PATENT COOPERATION TREATY

PCT/JP2003/015589



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference KW0112	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/015589	International filing date (day/month/year) 05 December 2003 (05.12.2003)	Priority date (day/month/year) 06 December 2002 (06.12.2002)
International Patent Classification (IPC) or national classification and IPC C07D 211/58, 401/06, 401/14, 405/14, A61K 31/4468, 31/4545, 31/444, A61P 7/00, 7/06, 43/00		
Applicant KOWA CO., LTD.		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>6</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand 14 April 2004 (14.04.2004)	Date of completion of this report 24 September 2004 (24.09.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/015589

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item. ☐

☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:

- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

☒ The international application as originally filed/furnished

☐ the description:

pages \_\_\_\_\_

pages\* \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ the claims:

pages \_\_\_\_\_

pages\* \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ the drawings:

pages \_\_\_\_\_

pages\* \_\_\_\_\_, as originally filed/furnished

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (specify): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (specify): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (specify): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (specify): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/015589

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 31-45

because:

☒ the said international application, or the said claims Nos. 31-45  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See supplemental sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 31-45

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the  
Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with  
the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ see Supplemental Box for further details.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP 03/15589

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III. 1.

The inventions set forth in claims 31-45 pertain to methods for treatment of the human body by therapy.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP 03/15589

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	1-30	YES
	Claims		NO
Inventive step (IS)	Claims	1-30	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-30	YES
	Claims		NO

## 2. Citations and explanations

1. US 6395753 B1
2. WP 01/00589 A1
3. JP 11-171774 A

## Claims 1-30

Although document 1 discloses the fact that compounds represented by general formula (1) in the present application have an inhibiting action on cell adhesion or cell infiltration, and that medicaments having said compounds as an active ingredient are efficacious in the treatment of disorders such as asthma, allergies, rheumatism, arteriosclerosis, inflammation and Sjögren's syndrome, it does not mention that the inhibiting action on cell adhesion or cell infiltration is pharmacologically closely associated with treatment of anaemia or disorders arising from depressed erythropoietin (EPO) production.

Documents 2 and 3, on the other hand, disclose agents for treating anaemia by heightening sensitivity to EPO; however these have a basic structure which differs from compounds represented by general formula (1) in the present application.

Moreover, even when the disclosures in documents 1-3 are considered together, the use of compounds represented by general formula (1) in the present application as



**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

International application No.

PCT/JP 03/15589

therapeutic agents for anaemia or disorders arising from depressed EPO production cannot be considered obvious to a person skilled in the art.

Therefore, the inventions set forth in claims 1-30 in the present application are novel and involve an inventive step relative to documents 1-3.